



7-13-05 AS-

IF 1617

PTO/SB/21 (02-04)

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| TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i> | Application Number | 09/841,426 | |
| | Filing Date | April 24, 2001 | |
| | First Named Inventor | Jonathan W. Nyce | |
| | Art Unit | 1617 | |
| | Examiner Name | Shaojia A. Jiang | |
| Total Number of Pages in This Submission | | Attorney Docket Number | 30775-701.501 |

| ENCLOSURES (Check all that apply) | | |
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| <input type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> After Allowance communication to Technology Center (TC) |
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| <input type="checkbox"/> Certified Copy of Priority Document(s) | Remarks | |
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| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | | |

| SIGNATURE OF APPLICANT, ATTORNEY OR AGENT | |
|---|--|
| Firm or Individual name | Albert P. Halluin, Reg. No. 25,227, WILSON SONSINI GOODRICH & ROSATI |
| Signature | |
| Date | 7/11/05 |

| CERTIFICATE OF TRANSMISSION/MAILING | | | |
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| Typed or printed name | Abigail Cruz | | |
| Signature | | Date | 7/11/05 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT

Attorney Docket No. 30775-701.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|----------------------------|
| In re Application |) | <u>PATENT APPLICATION</u> |
| |) | |
| Inventor(s): Jonathan W. Nyce |) | |
| |) | Art Unit: 1617 |
| Application No.: 09/841,426 |) | |
| |) | Examiner: Shaojia A. Jiang |
| Filed: April 24, 2001 |) | |
| |) | |
| Title Compositions & Formulations with an |) | |
| Epiandrosterone or a Ubiquinone & Kits & Their |) | |
| Use for Treatment of Asthma Symptoms & |) | |
| <u>Reducing Adenosine/Adenosine Receptor Levels</u> |) | |

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

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01 FC:1806 180.00 DA

- ☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
- ☐ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; or
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- ☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed.)

- ☒ There are no listed references which are not in the English language (**English abstract provided for JP 53 020432**).
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30775-701.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 7/11/05

By: Albert P. Halluin
Albert P. Halluin

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Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971



CERTIFICATION

(Attachment to Information Disclosure Statement)

- ☒ 37 C.F.R. §1.97(e)(1). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☐ 37 C.F.R. §1.97(e)(2). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing this certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement.

Respectfully submitted,

Dated:

7/14/05

By:

Albert P. Halluin

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| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 09/841,426 |
| | | | | Filing Date | April 24, 2001 |
| | | | | First Named Inventor | Jonathan W. Nyce |
| | | | | Art Unit | 1617 |
| | | | | Examiner Name | Shaojia A. Jiang |
| Sheet | 2 | of | 2 | Attorney Docket Number | 30775-701.501 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | | KOO E., et al., "Experiences with Dehydroepiandrosterone Therapy in Steroid-Dependent Intrinsic Bronchial Asthma," Database Biosis 'Online', 1987, pages 1995-1997, Vol. 128, no. 38, Biosciences Information Service, Philadelphia, PA, US | |
| | | FEHER, K.G., et al., "Adrenocortical Function in Bronchial Asthma," Acta Medica Hungarica, 1983, pages 125-132, Vol. 40, no. 2-3, National Institute of Rheumatism and Physiotherapy, Budapest, Hungary | |
| | | CROWLEY S., et al., "Asthma and Adrenarche," Journal of Endocrinology, March 21-24, 1994, page Abstract P10, Vol. 140, no. SUPPL., 13 th Joint Meeting of the British Endocrine Societies, Bournemouth, England, UK | |
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| Examiner signature | | Date Considered | |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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